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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,449	03/28/2000	KATSUMI AOYAGI	594.352USWO	8016

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT 1648	PAPER NUMBER
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DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/509,449		AOYAGI ET AL.	
	Examiner		Art Unit	
	Zachariah Lucas		1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,21,23 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 22,24 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Currently, claims 18 and 20-29 are pending and under consideration.
2. In the prior action, mailed on November 15, 2005, claims 18 and 20-24 were pending; with claims 18, 20, 21, and 23 rejected; and claims 22 and 24 objected to as depending from rejected claims.
3. In the Response of May 15, 2006, the Applicant amended claims 21 and 23; and added new claims 25-29.
4. Claims 18 and 20-29 are pending and under consideration.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claims 18 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova (J Med Virol 55: 1-6) and Papatheodoridis (J Hepatol 24: 36-41, or of Simmonds (WO 93/10239), in view of Ling (GB 2 051 357) and Schönbrunner (GB 2 313 666), and further in view of either Lacroix (EP 0 507 615) or Seidel et al. (U.S. Patent 6,183,949). The Applicant traverses the rejection on the basis that the teachings

of Schönbrunner teach away from the presently claimed invention wherein the antibody used to detect the antigen in the sample binds the same antigen as is used for the detection of antibody in the sample. This argument is not found persuasive.

The Applicant's argument is based solely on the teachings of Schönbrunner. It is noted that an argument based on the teachings of single reference presented in traversal of an obviousness rejection based on a combination of references is not persuasive where the traversal fails to consider the teachings of the additional references. See e.g., MPEP § 2145 IV. In the present case, the Applicant's argument does not consider the additional teachings of the Ling reference as previously described (see e.g., the action mailed on July 28, 2004, page 6). In these teachings of the Ling reference, the reference specifically indicates that the antigen used to detect antibody may be the same antigen that is recognized by the antibody used to detect antigen. See e.g., Ling, abstract, and pages 1 (right column) and 2 (left column).

From these teachings, it would have been apparent to those in the art that the use of an antigen and antibody combination such as a recited in the current claims would represent a functional equivalent of the non-complimentary antigen and antibody suggested by Ling, and that such non-complimentary antigen and antibody represent a functionally equivalent combination to the different antigen and antibody related by the teachings of Schönbrunner. It is noted that it is *prima facie* obvious to modify references to substitute one functional equivalent for another. See e.g., MPEP 2144.06. Because those of ordinary skill in the art would have recognized that these antigen/antibody combinations were functional equivalents from the *combined* teachings of the indicated references, the Applicant's arguments relating to the lack of motivation found in the teachings of Schönbrunner are not found persuasive.

The rejection is therefore maintained for the reasons above and the reasons of record.

7. **(Prior Rejection- Maintained)** Claims 21 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either of Cheng et al. (U.S. 5,627,080). These claims have been amended to specify that the methods involves the use of “non-ionic surfactants with an HLB value of 12 to 14 or at the concentration of 0.5% or greater.” The Applicant traverses the rejection on the same grounds as asserted with respect to the rejection of claims 18 and 20 above, and on the basis of the additional language added to the claims. These arguments are not found persuasive. The rejection is therefore maintained against claims 21 and 23, and is extended to new claims 25-28, which read on substantially the same subject matter as the previously rejected claims.

The first argument in traversal, regarding the teachings of Schönbrunner, is not found persuasive for the reasons indicated above.

The second argument in traversal, regarding the additional limitations on the non-ionic surfactants are not found persuasive as the Applicant has not shown that either the indicated HLB value or concentration would independently suffice to achieve the asserted unexpected results. The application discloses the results only in examples wherein the non-ionic detergent meets both of these limitations. For these reasons, and for the reasons presented on pages 6-7 of the prior action, the rejection is maintained.

Conclusion

8. No claims are allowed. Claims 22, 24, and 29 are objected to as depending on rejected claims.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

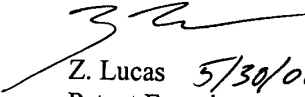
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas 5/30/06
Patent Examiner


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